K113863

510(k) Summary

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This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter:
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Purpose of submission: New device

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Preparation date: 09/10/2012 (amended on 09/28/2012)

Device name (assay kits):

Proprietary name:	QUANTA Flash™ DGP IgA QUANTA Flash™ DGP IgG
Common name:	DGP IgA Chemiluminescent Immunoassay DGP IgG Chemiluminescent Immunoassay
Classification name:	Antibodies, Gliadin (21 CCFR 862.1690)

Regulation Description	Radioallergosorbent (RAST) immunological test system
Regulation Medical Specialty	Immunology
Review Panel	Immunology
Product Code	MST
Regulation Number	866.5750
Device Class	2

Device name (Calibrators):

Proprietary name:	QUANTA Flash™ DGP IgA Calibrators QUANTA Flash™ DGP IgG Calibrators
Common name:	DGP IgA Calibrators DGP IgG Calibrators
Classification name:	Calibrator, secondary

Regulation Description	Calibrator
Regulation Medical Specialty	Clinical Chemistry
Product Code	JIT
Regulation Number	862.1150
Device Class	2

Device name (Controls):	Proprietary name:	QUANTA Flash™ DGP IgA Controls QUANTA Flash™ DGP IgG Controls
	Common name:	DGP IgA Controls DGP IgG Controls
	Classification name:	single (specified) analyte controls (assayed and unassayed)

Regulation Description	Quality control material (assayed and unassayed)
Regulation Medical Specialty	Clinical Chemistry
Product Code	JJX
Regulation Number	862.1660
Device Class	1

Predicate device(s): QUANTA Lite™ Gliadin IgA II, 510(k) number: K052143
QUANTA Lite™ Gliadin IgG II, 510(k) number: K052142

Device description:
Synthetic deamidated gliadin peptide is coated onto the surface of paramagnetic beads (microparticles), which are stored in the reagent cartridge under conditions that preserve the antigen in its reactive state. The reagent cartridge is then loaded onto and used by the BIO-FLASH® instrument.

Serum samples are prediluted by the instrument with system rinse buffer, and added to disposable plastic cuvettes. Small amounts of the diluted patient serum, the DGP beads, and assay buffer are all combined into a second cuvette, and mixed. This cuvette is incubated at 37°C. The beads are then magnetized and washed several times. Isoluminol conjugated anti-human IgA (or IgG) antibody is then added to the cuvette, and incubated at 37°C. Again, the beads are magnetized and washed repeatedly. The isoluminol conjugate produces a luminescent reaction when reagents ("Triggers") are added to the cuvette. The light produced from this reaction is measured as Relative Light Units (RLU) by the BIO-FLASH optical system. The RLU are proportional to the amount of bound isoluminol conjugate, which in turn is proportional to the amount of anti-DGP antibodies bound to the DGP on the beads.

For quantitation, the QUANTA Flash DGP IgA and IgG assays utilize a predefined lot specific Master Curve that is uploaded onto the instrument through the reagent cartridge barcode. Every new lot number of reagent cartridge must be calibrated before first use with the QUANTA Flash DGP IgA and IgG Calibrators. Based on the results obtained with the two Calibrators included in the Calibrator set, an instrument specific Working Curve is created, which is used to calculate chemiluminescent units (CU)

from the RLU obtained for each patient.

The QUANTA Flash DGP IgA reagent cartridge contains the following reagents:

a. DGP coated paramagnetic beads in buffer, containing protein stabilizers and preservative.
b. Assay buffer – colored pink, containing Tris-buffered saline, Tween 20, protein stabilizers and preservatives.
c. Tracer IgA – Isoluminol labeled anti-human IgA antibodies in buffer, containing protein stabilizers and preservative.

The QUANTA Flash DGP IgG reagent cartridge contains the following reagents:

a. DGP coated paramagnetic beads in buffer, containing protein stabilizers and preservative.
b. Assay buffer – colored pink, containing Tris-buffered saline, Tween 20, protein stabilizers and preservatives.
c. Tracer IgG – Isoluminol labeled anti-human IgA antibodies in buffer, containing protein stabilizers and preservative.

The QUANTA Flash™ DGP IgA Calibrators and the QUANTA Flash™ DGP IgG Calibrators kits each contain 2 vials of Calibrators:

QUANTA Flash™ DGP IgA Calibrators:

- QUANTA Flash DGP IgA Calibrator 1: Two (2) barcode labeled tubes containing 0.3 mL prediluted, ready to use reagent. Calibrators contain human IgA antibodies to DGP in buffer, protein stabilizers, and preservatives.
- QUANTA Flash DGP IgA Calibrator 2: Two (2) barcode labeled tubes containing 0.3 mL prediluted, ready to use reagent. Calibrators contain human IgA antibodies to DGP in buffer, protein stabilizers, and preservatives.

QUANTA Flash™ DGP IgG Calibrators:

- QUANTA Flash DGP IgG Calibrator 1: Two (2) barcode labeled tubes containing 0.3 mL prediluted, ready to use reagent. Calibrators contain human IgG antibodies to DGP in buffer, protein stabilizers, and preservatives.
- QUANTA Flash DGP IgG Calibrator 2: Two (2) barcode labeled tubes containing 0.3 mL prediluted, ready to use reagent. Calibrators contain human IgG antibodies to DGP in buffer, protein stabilizers, and preservatives.

The QUANTA Flash™ DGP IgA Controls kit and the QUANTA Flash™ DGP IgG Controls kits each contain 2 vials of Negative Control and two vials of Positive Control:

QUANTA Flash™ DGP IgA Controls:

QUANTA Flash™ DGP IgA Negative Control: Two (2) barcode labeled tubes containing 0.5 mL, ready to use reagent. Controls contain human IgA antibodies to DGP in buffer, protein stabilizers, and preservatives.

QUANTA Flash™ DGP IgA Positive Control: Two (2) barcode labeled tubes containing 0.5 mL, ready to use reagent. Controls contain human IgA antibodies to DGP in buffer, protein

stabilizers, and preservatives.

QUANTA Flash™ DGP IgG Controls:

QUANTA Flash™ DGP IgG Negative Control: Two (2) barcode labeled tubes containing 0.5 mL, ready to use reagent. Controls contain human IgG antibodies to DGP in buffer, protein stabilizers, and preservatives.

QUANTA Flash™ DGP IgG Positive Control: Two (2) barcode labeled tubes containing 0.5 mL, ready to use reagent. Controls contain human IgG antibodies to DGP in buffer, protein stabilizers, and preservatives.

Intended use:

The QUANTA Flash™ DGP IgA is a chemiluminescent immunoassay for the semi-quantitative determination of of IgA antibodies to synthetic, deamidated gliadin peptides in human serum. The measurement of IgA deamidated gliadin peptide antibodies can be used in conjunction with clinical findings and other laboratory tests to aid in the diagnosis of celiac disease and dermatitis herpetiformis.

The QUANTA Flash™ DGP IgG is a chemiluminescent immunoassay for the semi-quantitative detection of IgG antibodies to synthetic, deamidated gliadin peptides in human serum. The measurement of IgG deamidated gliadin peptide antibodies can be used in conjunction with clinical findings and other laboratory tests to aid in the diagnosis of celiac disease in IgA sufficient and IgA deficient patients, as well as dermatitis herpetiformis.

The QUANTA Flash DGP IgA Calibrators are intended for use with the QUANTA Flash DGP IgA chemiluminescent immunoassay (CIA). Each calibrator establishes a point of reference for the working curve that is used to determine Chemiluminescent Unit (CU) values in the measurement of IgA anti-DGP antibodies in serum.

The QUANTA Flash DGP IgA Calibrators are intended for use with the QUANTA Flash DGP IgA chemiluminescent immunoassay (CIA). Each calibrator establishes a point of reference for the working curve that is used to determine Chemiluminescent Unit (CU) values in the measurement of IgA anti-DGP antibodies in serum.

The QUANTA Flash DGP IgA Controls are intended for quality control purposes of the QUANTA Flash DGP IgA chemiluminescent immunoassay (CIA) kit run on the BIO FLASH® instrument that is used for the measurement of IgA anti-deamidated gliadin peptide (DGP) antibodies in human serum.

The QUANTA Flash DGP IgG Controls are intended for quality control purposes of the QUANTA Flash DGP IgG chemiluminescent immunoassay (CIA) kit run on the BIO FLASH® instrument that is used for the measurement of IgG anti-deamidated gliadin peptide (DGP) antibodies in human serum.

Substantial equivalence:

The QUANTA Flash™ DGP IgA assay, the QUANTA Flash DGP IgA Calibrators and the QUANTA Flash DGP IgA Controls have the same intended use and assay principle as the predicate device.
The QUANTA Flash™ DGP IgG assay, the QUANTA Flash DGP IgAG Calibrators and the QUANTA Flash DGP IgG Controls have the same intended use and assay principle as the predicate device.

Comparison to predicate device:

QUANTA Flash DGP IgA reagent kit

Similarities		
Item	**QUANTA Flash DGP IgA**	**Predicate Device**
Intended use	Semi-quantitative determination of IgA antibodies to synthetic, deamidated gliadin peptides in human serum.	Semi-quantitative detection of IgA antibodies to gliadin in human serum
Assay methodology	Solid phase (heterogenous) immunoassay	Solid phase (heterogeneous) immunoassay
Traceability	International Reference Preparation is not available	International Reference Preparation is not available
Antigen	Synthetic, deamidated gliadin peptides	Synthetic, deamidated gliadin peptides
Sample type	Serum	Serum
Shelf life	One year	One year

Differences		
Item	**QUANTA Flash DGP IgA**	**Predicate Device**
Detection/ Operating principle	Chemiluminescent immunoassay	Enzyme-linked immunosorbent assay
Solid phase	Paramagnetic microparticles (beads)	96-well plate
Conjugate	Isoluminol conjugated anti-human IgA	HRP conjugated anti-human IgA
Calibration	Lot specific Master Curve + two Calibrators (Sold separately)	Gliadin IgA II ELISA Low Positive Gliadin IgA II ELISA High Positive (Included in the kit)

QUANTA Flash DGP IgG reagent kit

Similarities		
Item	**QUANTA Flash DGP IgG**	**Predicate Device**
Intended use	Semi-quantitative determination of IgG antibodies to synthetic, deamidated gliadin peptides in human serum.	Semi-quantitative detection of IgG antibodies to gliadin in human serum
Assay methodology	Solid phase (heterogenous) immunoassay	Solid phase (heterogenous) immunoassay
Traceability	International Reference Preparation is not available	International Reference Preparation is not available
Antigen	Synthetic, deamidated gliadin peptides	Synthetic, deamidated gliadin peptides
Sample type	Serum	Serum
Shelf life	One year	One year

Differences		
Item	**QUANTA Flash DGP IgG**	**Predicate Device**
Detection/ Operating principle	Chemiluminescent immunoassay	Enzyme-linked immunosorbent assay
Solid phase	Paramagnetic microparticles (beads)	96-well plate
Conjugate	Isoluminol conjugated anti-human IgG	HRP conjugated anti-human IgG
Calibration	Lot specific Master Curve + two calibrators (Sold separately)	Gliadin IgG II ELISA Low Positive Gliadin IgG II ELISA High Positive (Included in the kit)

QUANTA Flash DGP IgA Calibrators

Item	**QUANTA Flash DGP IgA Calibrators**	**Predicate Device**
Intended use	For use with the QUANTA Flash DGP IgA chemiluminescent immunoassay (CIA). Each calibrator establishes a point of reference for the working curve that is used to determine Chemiluminescent Unit (CU) values in the measurement of IgA anti-DGP antibodies in serum.	No separate intended use; calibrators are part of the kit.
Analyte	DGP IgA antibodies	DGP IgA antibodies
Method	QUANTA Flash™ DGP IgA, chemiluminescent immunoassay	QUANTA Lite™ Gliadin IgA II, ELISA
Unit	CU (Chemiluminescent units) (arbitrary)	Units (arbitray)
Matrix	Human serum, buffer, stabilizers, preservative	Human serum, buffer, stabilizers, preservative
Physico-chemical characteristics	Liquid, ready to use	Liquid, ready to use
Storage	2-8 °C	2-8 °C
Shelf life	One year	One year
In-use stability	Four calibrations, maximum total 8 hours uncapped onboard the instrument.	Calibrators can be used until the end of the shelf life when stored properly

QUANTA Flash DGP IgG Calibrators

Item	**QUANTA Flash DGP IgG Calibrators**	**Predicate Device**
Intended use	For use with the QUANTA Flash DGP IgG chemiluminescent immunoassay (CIA). Each calibrator establishes a point of reference for the working curve that is used to determine Chemiluminescent Unit (CU) values	No separate intended use; calibrators are part of the kit.

	in the measurement of IgG anti-DGP antibodies in serum.	
Analyte	DGP IgG antibodies	DGP IgG antibodies
Method	QUANTA Flash™ DGP IgG, chemiluminescent immunoassay	QUANTA Lite™ Gliadin IgG II, ELISA
Matrix	Human serum, buffer, stabilizers, preservative	Human serum, buffer, stabilizers, preservative
Unit	CU (Chemiluminescent units) (arbitrary)	Units (arbitray)
Physico-chemical characteristics	Liquid, ready to use	Liquid, ready to use
Storage	2-8 °C	2-8 °C
Shelf life	One year	One year
In-use stability	Four calibrations, maximum total 8 hours uncapped onboard the instrument.	Calibrators can be used until the end of the shelf life when stored properly

QUANTA Flash DGP IgA Controls

Item	QUANTA Flash DGP IgA Controls	Predicate Device
Intended use	Quality control purposes of the QUANTA Flash DGP IgA chemiluminescent immunoassay (CIA) kit.	No separate intended use; controls are part of the kit.
Analyte	DGP IgA antibodies	DGP IgA antibodies
Method	QUANTA Flash™ DGP IgA, chemiluminescent immunoassay	QUANTA Lite™ Gliadin IgA II, ELISA
Unit	CU (Chemiluminescent units) (arbitrary)	Units (arbitray)
Matrix	Human serum, buffer, stabilizers, preservative	Human serum, buffer, stabilizers, preservative
Physico-chemical characteristics	Liquid, ready to use	Liquid, ready to use
Levels	2 (negative and positive)	3: (ELISA negative, low positive, high positive)
Storage	2-8 °C	2-8 °C
Shelf life	One year	One year
In-use stability	15 uses, with a maximum time of 10 minutes onboard the instrument per use, or 2 ½ hours, total.	Controls can be used until the end of the shelf life when stored properly

QUANTA Flash DGP IgG Controls

Item	QUANTA Flash DGP IgG Controls	Predicate Device
Intended use	Quality control purposes of the QUANTA Flash DGP IgG chemiluminescent immunoassay (CIA) kit.	No separate intended use; controls are part of the kit.
Analyte	DGP IgG antibodies	DGP IgG antibodies
Method	QUANTA Flash™ DGP IgG, chemiluminescent immunoassay	QUANTA Lite™ Gliadin IgG II, ELISA
Matrix	Human serum, buffer, stabilizers, preservative	Human serum, buffer, stabilizers, preservative
Unit	CU (Chemiluminescent units) (arbitrary)	Units (arbitray)
Physico-chemical characteristics	Liquid, ready to use	Liquid, ready to use
Levels	2 (negative and positive)	3: (ELISA negative, low positive, high positive)
Storage	2-8 °C	2-8 °C
Shelf life	One year	One year
In-use stability	15 uses, with a maximum time of 10 minutes onboard the instrument per use, or 2 ½ hours, total.	Controls can be used until the end of the shelf life when stored properly

Value assignment and traceability of Calibrators and Controls

The QUANTA Flash DGP IgA and IgG Calibrators and Controls are manufactured by diluting human serum that contains high titer of IgA or IgG anti-DGP antibodies into a buffer containing stabilizers and preservative. The human serum is obtained from commercial sources and it is tested for markers of infectious substances.
The target CU is achieved through trial dilutions on small scale. Once a dilution is selected, the Calibrators and Control are bulked, tested, and adjusted. Upon completion of the manufacturing process, the Calibrators and Controls are tested on at least two instruments, on at least two lots of reagent cartridge, in replicates of 10 to determine final value assignment.

There are currently no recognized international standards for the measurement of IgA and IgG anti-deamidated gliadin peptide antibodies.
Calibrator and Control values are directly traceable to in-house Standards that are used to create the Master Curve for the QUANTA Flash™ DGP IgA and QUANTA Flash™ DGP IgG assay.

Performance characteristics

Precision

The precision of the QUANTA Flash DGP IgA assay was evaluated on 8 samples containing various concentrations of DGP IgA antibodies in accordance with CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Procedures - Approved Guideline: samples were run in

duplicates, twice a day, for at least 20 days. Data were analyzed with the Analyse-it for Excel method evaluation software, and within run, between run, between day and total precisions are summarized in the Table below. All %CV values were within the acceptance limit, 15%.

			Within-Run Precision (repeatability)		Between-Run Precision		Between-Day Precision		Total Precision	
Sample ID	N	Mean(CU))	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	84	105.6	5.4	5.1%	0.0	0.0%	6.8	6.4%	8.6	8.2%
2	80	35.1	2.1	5.9%	0.0	0.0%	3.8	10.7%	4.3	12.2%
3	84	15.4	0.9	5.8%	0.0	0.0%	1.0	6.2%	1.3	8.5%
4	80	32.4	1.0	3.1%	0.3	0.8%	2.2	6.8%	2.4	7.5%
5	84	128.8	5.9	4.6%	4.1	3.2%	8.6	6.7%	11.2	8.7%
6	84	10.5	0.4	4.0%	0.2	1.9%	0.6	5.8%	0.8	7.3%
7	80	33.0	1.3	4.1%	0.0	0.0%	2.9	8.8%	3.2	9.7%
8	76	1930.8	94.9	4.9%	63.8	3.3%	149.7	7.8%	188.4	9.8%

The precision of the QUANTA Flash DGP IgG assay was evaluated on 8 samples containing various concentrations of DGP IgG antibodies in accordance with CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Procedures - Approved Guideline: samples were run in duplicates, twice a day, for at least 20 days. Data were analyzed with the Analyse-it for Excel method evaluation software, and within run, between run, between day and total precision are summarized in the Table below. All %CV values were within the acceptance limit, 15%.

			Within-Run Precision (repeatability)		Between-Run Precision		Between-Day Precision		Total Precision	
Sample ID	N	Mean (CU)	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	80	5.8	0.2	3.1%	0.1	2.5%	0.1	2.0%	0.3	4.5%
2	80	16.8	0.5	3.0%	0.1	0.5%	0.2	1.5%	0.6	3.3%
3	80	20.7	0.5	2.5%	0.3	1.3%	0.5	2.2%	0.7	3.6%
4	80	24.6	0.5	1.9%	0.5	1.8%	0.4	1.5%	0.7	3.0%
5	80	85.1	1.9	2.2%	0.8	0.9%	2.5	2.9%	3.2	3.8%
6	80	411.6	7.7	1.9%	6.8	1.6%	9.4	2.3%	13.9	3.4%
7	80	791.0	24.3	3.1%	16.2	2.0%	5.9	0.7%	29.8	3.8%
8	80	1781.4	52.1	2.9%	27.9	1.6%	48.3	2.7%	76.3	4.3%

Additionally, precision studies were also performed at three different testing sites to be able to calculate between-sites (between-instruments) precision. Results that were obtained in the research laboratory of INOVA were compared to those obtained on the same specimens in a hospital (Akron City Hospital, Summa Health System, 525 East Market Street, Akron, Ohio 44304) and in an academic laboratory (Mitogen Advanced Diagnostics Laboratory, The University of Calgary, Faculty of Medicine, #431,3330 Hospital Dr NW, Calgary, AB T2N 4N1, CANADA).

Three specimens (one negative, one around-the-cutoff low positive and one medium positive) were tested at each site. Samples were run in duplicates four times a day, for 10 days, resulting in 80 individual data points. Two reagent lots, two calibrator lots and two operators were included as variables at the INOVA site.
Between sites/instruments SD and %CV values were calculated with the *Analyse-it for Excel* software, and the results are presented below as pair-wise comparisons between the sites.
Moreover, total between-sites reproducibility was calculated based on the pair-wise comparisons, and it was used to calculate Total Reproducibility, taking into account within run, between run, between lots, between calibrator lots, between operators and between sites precision.
Acceptance criterion was ≤ 15% for all reproducibility studies.

DGP IgA, Sample 1

Blue: %CV Red: average (CU)

	INOVA	Mitogen Advanced Diagnostics	Summa Health System
INOVA		12.6	12.6
Mitogen Advanced Diagnostics	9.1		12.3
Summa Health System	7.6	5.0	

DGP IgA, Sample 2

Blue: %CV Red: average (CU)

	INOVA	Mitogen Advanced Diagnostics	Summa Health System
INOVA		25.4	25.1
Mitogen Advanced Diagnostics	5.4		25.0
Summa Health System	6.6	5.1	

DGP IgA, Sample 3

Blue: %CV Red: average (CU)

	INOVA	Mitogen Advanced Diagnostics	Summa Health System
INOVA		137.1	132.8
Mitogen Advanced Diagnostics	5.7		132.9
Summa Health System	7.6	6.9	

DGP IgG, Sample 1

Blue: %CV Red: average (CU)

	INOVA	Mitogen Advanced Diagnostics	Summa Health System
INOVA		13.0	12.8
Mitogen Advanced Diagnostics	6.3		12.5
Summa Health System	7.9	5.3	

DGP IgG, Sample 2

Blue: %CV Red: average (CU)

	INOVA	Mitogen Advanced Diagnostics	Summa Health Care
INOVA		20.5	20.2
Mitogen Advanced Diagnostics	5.6		19.7
Summa Health Care	7.5	5.2	

DGP IgG, Sample 3

Blue: %CV Red: average (CU)

	INOVA	Mitogen Advanced Diagnostics	Summa Health Care
INOVA		118.4	114.1
Mitogen Advanced Diagnostics	4.7		113.5
Summa Health Care	7.7	7.2	

DGP IgA Total Reproducibility summary table:

			Within Run		Between Run		Between Reagent Lots		Between Calibrator Lots		Between Operators		Between Sites		Total	
Sample	Mean (CU)	Number of replicates	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)
Sample #1	12.9	80	0.8	6.4	0.7	5.2	0.4	3.1	0.7	5.6	0.8	5.8	1.1	9.1	1.9	14.8
Sample #2	25.5	80	1.0	3.8	1.4	5.5	1.1	4.1	1.6	6.3	0.6	2.3	1.8	7.0	3.2	12.6
Sample #3	136.8	80	4.0	2.9	8.9	6.5	7.5	5.5	10.4	7.6	4.4	3.2	11.2	8.3	20.1	14.7

DGP IgG Total Reproducibility summary table:

			Within Run		Between Run		Between Reagent Lots		Between Calibrator Lots		Between Operators		Between Sites		Total	
Sample	Mean (CU)	Number of replicates	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)	SD (CU)	CV (%)
Sample #1	13.4	80	0.3	2.6	0.8	5.9	0.5	4.0	1.0	7.5	0.5	3.6	1.0	8.1	1.8	13.5
Sample #2	21.0	80	0.5	2.3	1.2	5.5	0.7	3.5	1.5	7.3	0.8	4.0	1.5	7.6	2.7	12.9
Sample #3	118.9	80	2.8	2.4	5.9	4.9	2.8	2.3	2.8	2.3	4.7	4.0	9.4	8.1	13.0	10.9

Limit of Blank, Limit of Detection

QUANTA Flash DGP IgA:

The Limit of Detection (LoD) of the QUANTA Flash™ DGP IgA assay is 730.3 RLU, which is below the analytical measuring range of the assay. It was determined consistent with CLSI EP17-A guideline with proportions of false positives (alpha) less than 5% and false negatives (beta) less than 5%; based on 140 determinations, with 60 blank and 80 low level samples. The LoB is 504.9 RLU.

QUANTA Flash DGP IgG:

The Limit of Detection (LoD) of the QUANTA Flash™ DGP IgG assay is 469.2 RLU, which is below the analytical measuring range of the assay. It was determined consistent with CLSI EP17-A guideline with proportions of false positives (alpha) less than 5% and false negatives (beta) less than 5%; based on 140 de

terminations, with 60 blank and 80 low level samples. The LoB is 257.7 RLU.

Analytical Measuring Range

QUANTA Flash DGP IgA: 5.2 CU - 2367.3 CU

QUANTA Flash DGP IgG: 2.8 CU -1936.7 CU

Cut-off, reference range

QUANTA Flash DGP IgA:	Negative	<20 CU
	Weak Positive	20-30 CU
	Positive	>30 CU
QUANTA Flash DGP IgG :	Negative	<20 CU
	Weak Positive	20-30 CU
	Positive	>30 CU

QUANTA Flash DGP IgA
The control population for establishing the reference interval for the DGP IgA assay consisted of 355 subjects:

Apparently healthy blood bank donors	201
Inflammatory bowel disease	14
H. pylori infection	9
Autoimmune thyroid disease	18
Infectious diseases	28
Rheumatoid arthritis	30
Patients with antinuclear antibodies	5
Controls tTG workshop study from Dr. Liu at Children's Hospital and University of Colorado.	50

All specimens were the same matrix (serum) as specified in the Intended Use. All specimens were unaltered. The cut off was established in accordance to CLSI C28-A3c: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline - Third Edition. The Analyse-it for Excel software was used to make the calculations. The distribution of the results was non-normal (Saphiro-Wilk $p<0.0001$), so the non-parametric percentile method was used. The 99th percentile of the RLU values was 6777. To ensure high specificity, the 8000 RLU value was selected as cut-off. This value provided the combination of the highest sensitivity and specificity based on the results obtained on 37 CD specimens that were tested together with the control population. The value of 20 chemiluminescent units

(CU) was assigned to 8000 RLU.

QUANTA Flash DGP IgG
The control population for establishing the reference interval for the DGP IgA assay consisted of 392 subjects:

Apparently healthy blood bank donors	201
Inflammatory bowel disease	14
H. pylori infection	9
Autoimmune thyroid disease	18
Controls tTG workshop study from Dr. Liu at Children's Hospital and University of Colorado.	50

All specimens were the same matrix (serum) as specified in the Intended Use. All specimens were unaltered. The cut off was established in accordance to CLSI C28-A3c: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline - Third Edition. The Analyse-it for Excel software was used to make the calculations. The distribution of the results was non-normal (Saphiro-Wilk $p<0.0001$), so the non-parametric percentile method was used. The 99th percentile of the RLU values was 19451, and the 98th percentile value was 9800. The cut-off was finally established at 15000 RLU. This value provided the combination of the highest sensitivity and specificity based on the results obtained on 37 CD specimens that were tested together with the control population. The value of 20 chemiluminescent units (CU) was assigned to 15000 RLU.

Linearity

QUANTA Flash DGP IgA:

The linearity of the AMR was evaluated by a study according to CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. Six serum samples with various DGP IgA concentrations were diluted with a low negative serum to obtain values that cover the whole AMR. All specimens showed dilution linearity individually, and the combined data yielded the following results with linear regression:

Sample	Test Range (CU)	Slope (95% CI)	Y-intercept (95% CI)	R^2
All Samples	5.2 to 2596.8	1.05 (1.03 to 1.07)	6.19 (-8.49 to 20.86)	0.99

QUANTA Flash DGP IgG:

The linearity of the AMR was evaluated by a study according to CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. Six serum samples with various DGP IgG concentrations were diluted with a low negative serum to obtain values that cover the whole AMR. All six specimens showed dilution linearity individually, and the combined data yielded the following results with linear regression:

Sample	Test Range (CU)	Slope (95% CI)	Y-intercept (95% CI)	R^2
All Samples	3.6 to 2565.4	1.03 (1.02 to 1.04)	4.78 (-4.99 to 14.54)	1.00

Auto-rerun function

The BIO-FLASH software has an Auto-rerun option available. If this option is selected, the instrument will automatically rerun any sample that has a result >2367.3 CU for DGP IgA or >1936.7 for DGP IgG, by further diluting it by a factor of 10, and calculating the actual CU using this additional dilution factor.

To confirm the Auto-rerun function, two high positive specimens with results above the analytical measuring range were selected for each assay. The samples were run with the Auto-rerun function enabled on the BIO-FLASH. Then the specimens were manually diluted the same way as it happens in the Auto-rerun function (10 fold dilution), and tested on the BIO-FLASH. The results were within the analytical measuring range after auto-rerun or manual dilution for all specimens. The differences between the manual and automatic results for DGP IgA were 11% and 15%, and for the DGP IgG 19% and 5% (within the ± 20% acceptance limit).

High concentration hook effect

To assess hook effect, the measurement signal (relative light units, RLU) was examined for high positive specimens with results above the analytical measuring range before and after automatic or manual dilution. All sera produced significantly higher RLU values when used "as is" compared to the manually or automatically diluted ones, thereby confirming that high positive specimens above the analytical measuring range do not show hook effect up to 5167.2 CU in the DGP IgA assay and up to 4323.7 CU in the DGP IgG assay.

Interference

QUANTA Flash DGP IgA:

The interference study was performed according to CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition. Three specimens were tested. Interfering substances were spiked into every specimen at three different concentrations in 10% of total specimen volume, and the resulting samples were assessed in triplicates with the DGP IgG assay. Recovery of the unit values was calculated compared to control samples spiked with the same volume of diluents. Acceptance criteria for the interference studies were 85% - 115% recovery, or +/- 4 CU difference, whichever is greater.

No interference was detected with hemoglobin up to 200 mg/dL (recovery 88.9-114.4%) and triglycerides up to 1000 mg/dL and cholesterol up to 224.3 mg/dL (recovery 100.2-110.1%). No interference was detected with bilirubin up to 10 mg/dL (recovery: 96.0-114.6%) in two specimens. One specimen showed 116.1% recovery when spiked with 5 mg/dl bilirubin; however, no interference could be detected when the same specimen was spiked with 10 mg/dL bilirubin (recovery 109.9%) or when the other specimens were spiked with the same concentration of bilirubin. No interference was detected with RF IgM up to 500 IU/mL (recovery 86.8-98.5%). One specimen showed 76.3% recovery when spiked with 500 IU/mL RF; however, no interference was detected when the same specimen was spiked with 100 and 300 IU/mL RF (recovery 94.1 and 98.5%), or when the other two specimens were spiked with 500 IU/mL.

QUANTA Flash DGP IgG:

The interference study was performed according to CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition. Five specimens were tested. One specimen (6.2 CU) was excluded from the final calculations, as some of the measurement results were below the analytical measuring range (5.2 CU). Interfering substances were spiked into every specimen at three different concentrations in 10% of total specimen volume, and the resulting samples were assessed in triplicates with the DGP IgG assay. Recovery of the unit values was calculated compared to control samples spiked with the same volume of diluents. Acceptance criteria for the interference studies were 85% - 115% recovery, or +/- 4 CU difference, whichever is greater.

No interference was detected with bilirubin up to 10 mg/dL (recovery: 104-108%), hemoglobin up to 200 mg/dL (recovery 100-110%), triglycerides up to 1000 mg/dL (recovery 104-107%), and cholesterol up to 224.3 mg/dL (recovery 104-107%). No interference was detected with RF IgM up to 500 IU/mL in three specimens (recovery 99-112%). One specimen showed 137% recovery when spiked with 100 IU/mL RF only; however, no interference was detected when the same specimen was spiked with 300 and 500 IU/mL RF (recovery 108% and 112%), or when the other three specimens were spiked with the same concentration of RF.

Cross-reactivity

QUANTA Flash DGP IgA:

To test potential cross-reactivity with autoantibodies and infection-induced antibodies, 201 patient samples were tested from patients with infectious diseases, autoimmune diseases and connective tissue diseases, including those characterized with gastrointestinal symptoms. None of those specimens were positive in the DGP IgA test.

QUANTA Flash DGP IgG:

To test potential cross-reactivity with autoantibodies and infection-induced antbodies, 185 patient samples were tested from patients with infectious diseases, autoimmune diseases and connective tissue diseases, including those characterized with gastrointestinal symptoms. Two out of the 31 viral hepatitis, two out of the 17 H. pylori infection, and one out of the 37 rheumatoid arthritis specimens were positive with the DGP IgG assay. Altogether, only five out of the 185 specimens (3%) were positive, indicating the lack of cross-reactivity.

Comparison with predicate device

QUANTA Flash DGP IgA:

Samples for method comparison analysis included those samples from the clinical validation studies (CD, non-CD and dermatitis herpetiformis patients) that were within the AMR of the QUANTA Flash DGP IgA assay. These samples were tested on both the QUANTA Flash DGP IgA and on the predicate ELISA.

Method Comparison (N=96)		DGP IgA ELISA			Percent Agreement (95% Confidence)
		Positive	Negative	Total	
QUANTA Flash™ DGP IgA CIA	Positive	65	3*	68	Pos. Agreement = 91.5% (82.5-96.8%)
	Negative	6**	28	34	Neg. Agreement = 90.3% (74.2-98.0%)
	Total	71	31	102	Total Agreement = 91.2% (83.9-95.9%)

* Two patients are suspected CD with no diagnosis, while the third is a DH patient.

** Two patients have DH. Three patients have CD, two without clinical presentation, one with a Marsh III biopsy. One patient has ulcerative colitis.

DGP IgA method comparison on DH samples:

Method Comparison (N=21)		DGP IgA ELISA			Percent Agreement (95% Confidence)
		Positive	Negative	Total	
QUANTA Flash™ DGP IgA CIA	Positive	12	1	13	Pos. Agreement = 85.7% (57.2%-98.2%)
	Negative	2	6	8	Neg. Agreement = 85.7% (42.1-99.6%)
	Total	14	7	21	Total Agreement = 85.7% (63.7%-97.0%)

QUANTA Flash DGP IgG:

Samples for method comparison analysis included those samples from the clinical validation studies (CD, non-CD and DH patients) that were within the AMR of the QUANTA Flash DGP IgG assay. These samples were tested on both the QUANTA Flash DGP IgG and on the predicate ELISA.

Method Comparison (N=235)		DGP IgG ELISA			Percent Agreement (95% Confidence)
		Positive	Negative	Total	
QUANTA Flash™ DGP IgG CIA	Positive	78	26*	104	Pos. Agreement = 95.1% (88.0-98.7%)
	Negative	4**	133	137	Neg. Agreement = 83.6% (77.0-89.0%)
	Total	82	159	241	Total Agreement = 87.6% (82.7-91.4%)

*Thirteen samples are from CD patients; three being on GFD. One sample is from a suspected CD patient that is IgA anti-DGP positive. Two samples have H. pylori gastritis, two have viral hepatitis, and one has rheumatoid arthritis. One patient, with low blood count, is IgG anti-h-tTG positive. The remaining 6 samples are from apparently healthy individuals; one had gastrointestinal symptoms at time of sample collection, with two being IgA anti-h-tTG positive.

**Three samples are from CD patients, and one is from a DH patient.

DGP IgG method comparison on DH samples:

Method Comparison (N=21)		DGP IgG ELISA			Percent Agreement (95% Confidence)
		Positive	Negative	Total	
QUANTA Flash™ DGP IgG CIA	Positive	16	0	16	Pos. Agreement = 88.9% (65.3%-98.6%)
	Negative	2	5	7	Neg. Agreement = 100.0% (47.8%-100.0%)
	Total	18	5	23	Total Agreement = 91.3% (72.0%-98.9%)

DGP IgG method comparison on IgA deficient samples:

Method Comparison (N=21)		DGP IgG ELISA			Percent Agreement (95% Confidence)
		Positive	Negative	Total	
QUANTA Flash™ DGP IgG CIA	Positive	5	2	7	Pos. Agreement = 71.4% (29.0%-96.3%)
	Negative	2	4	6	Neg. Agreement = 66.7% (22.3%-95.7%)
	Total	7	6	13	Total Agreement = 69.2% (38.6%-90.9%)

Clinical sensitivity, specificity

QUANTA Flash DGP IgA:

The clinical validation study included 54 CD samples from INOVA's serum library, 39 samples from patients with CD but on gluten free diet or with unconfirmed CD, 103 non-celiac disease controls, and 21 samples from patients with DH. A separate external study included 93 CD samples, 151 samples from individuals seeking medical attention in whom CD was excluded based on physical exam and diagnostic tests, and 98 disease controls. The 151 samples consisted of 58 samples from adults and 93 samples from pediatric population. Clinical symptoms of these subjects were consistent with suspected CD:

gastrointestinal symptoms, fatigue, and/or anemia. These samples were tested with the QUANTA Flash DGP IgA CIA. Results obtained on healthy blood donors were not included in the clinical sensitivity and specificity calculations. None of the control samples were positive in the DGP IgA assay.
The results were analyzed to calculate sensitivity and specificity for CD (n=147) and DH (n=21) separately using the same control population (n=352).
When divided according to age, the QUANTA Flash™ DGP IgA test was performed on 43 serum samples from infants, 96 serum samples from children, 36 serum samples from adolescents, and 324 serum samples from adults. Sera from all pediatric groups showed similar sensitivity and specificity values as of the adult population, thereby demonstrating the utility of the same cut-off (20 CU). The results of this testing are shown in the Tables below:

Clinical sensitivity and specificity of the QUANTA Flash™ DGP IgA assay in CD:

		Diagnosis			Analysis (95% confidence)
		CD	Not CD	Total	
QUANTA Flash™ DGP IgA	Positive	105	0	105	Sensitivity = 71.4% (63.4-78.6%)
	Negative	42*	352	394	Specificity = 100.0% (99.0-100%)
	Total	147	352	499	

*Of 21 patients with ELISA data, 18 were DGP IgA EIA negative. Of the 21 patients with no ELISA data, 6 had Marsh III, 4 had Marsh II, and 11 had no biopsy result.

The distribution and DGP IgA positivity rate in the disease control population:

Patient Group	N	# of positives
Autoimmune liver disease	5	0
Viral hepatitis	47	0
Inflammatory bowel disease (Chron +UC)	17	0
H pylori infection	17	0
Food allergy	9	0
Systemic rheumatic disease	12	0
Autoimmune thyroid disease	22	0
Patients with gastrointestinal symptoms	11	0
Type 1 diabetes mellitus	14	0
Rheumatoid arthritis	37	0
Other infectious disease (HIV, Syphilis)	10	0
Total	**201**	**0**

Summary of sensitivity and specificity values in CD according to age groups:

Age group	DGP IgA	
	Sensitivity, %	Specificity, %
1 month – 2 years	50.0	100.0
2 years – 12 years	66.7	100.0
12-21 years	58.3	100.0
>21 years	77.4	100.0
< 21 years (total)	63.5	100.0
Total	71.4	100.0

Diagnostic sensitivity and specificity were calculated on the DH group separately, and the results are shown in the Table below.

Clinical sensitivity and specificity of the QUANTA Flash™ DGP IgA assay in DH:

		Diagnosis			Analysis (95% confidence)
		DH	Not DH	Total	
QUANTA Flash™ DGP IgA	Positive	13	0	13	Sensitivity = 61.9% (38.4-81.9%)
	Negative	8*	352	360	Specificity = 100.0% (99.0-100%)
	Total	21	352	373	
*Six samples were also negative on the DGP IgA EIA.					

ROC analysis was performed on the validation sample pool for CD and DH (excluding CD patients on gluten-free diet). The results are below:

Celiac Disease:

Test	Area	95% CI	SE	Z	p
DGP IgA	0.94	0.90 to 0.97	0.018	24.93	<0.0001

Dermatitis Herpetiformis:

Test	Area	95% CI	SE	Z	p
DGP IgA	0.79	0.63 to 0.96	0.082	3.57	0.0002

QUANTA Flash DGP IgG:

The clinical validation study included 62 CD samples from INOVA's serum library (including 7 with selective IgA deficiency), 87 non-celiac disease controls, 39 samples from patients with CD but on gluten free diet or with unconfirmed CD, and 23 samples from patients with DH. A separate external study included 102 CD samples (including 9 with selective IgA deficiency), 151 samples from individuals seeking medical attention in whom CD was excluded after physical exam and diagnostic tests, and 98 disease controls. The 151 samples consisted of 58 samples from adults and 93 samples from pediatric population. Clinical symptoms of these subjects were consistent with suspected CD: gastrointestinal symptoms, fatigue, and/or anemia. These samples were tested with the QUANTA Flash DGP IgG CIA. Results obtained on healthy blood donors were not included in the clinical sensitivity and specificity calculations. Four of the control samples were weak positive (< 30.0 CU) in the DGP IgG assay.
The results were analyzed to calculate sensitivity and specificity for CD (n=148), CD with IgA deficiency (n=16) and DH (n=23) separately using the same control population (n=336).
When divided according to age, the QUANTA Flash™ IgG test was performed on 43 serum samples from infants, 96 serum samples from children, 35 serum samples from adolescents and 310 serum samples from adults. Sera from all pediatric groups showed similar sensitivity and specificity values as of the adult population, thereby demonstrating the utility of the same cut-off (20 CU).

Clinical sensitivity and specificity of the QUANTA Flash DGP IgG assay in CD:

		Diagnosis			Analysis (95% confidence)
		CD	Not CD	Total	
QUANTA Flash™ DGP IgG	Positive	132	9*	141	Sensitivity = 89.2% (83.0-93.7%)
	Negative	16**	327	343	Specificity = 97.3% (95.0-98.8%)
	Total	148	336	484	

* Two samples have H. pylori gastritis, two have viral hepatitis, and one has rheumatoid arthritis.

**Of 13 patients with ELISA data, 10 were DGP IgG EIA negative. Of the 10 patients with no ELISA data, 1 had Marsh III, 2 had Marsh II, and 7 had no biopsy result.

Altogether 16 samples were from IgA deficient CD patients. Nine out of 16 (56.3%) were positive with the DGP IgG assay, indicating that the assay is a useful tool for CD screening in IgA deficient subjects.

Clinical sensitivity and specificity of the QUANTA Flash DGP IgG assay in IgA deficient CD:

		Diagnosis			Analysis (95% confidence)
		CD (IgA deficient)	Not CD	Total	
QUANTA Flash™ DGP IgG	Positive	9	9	18	Sensitivity = 56.3% (29.9-80.2%)
	Negative	7	327	334	Specificity = 97.3% (95.0-98.8%)
	Total	16	336	352	

The distribution and positivity rate in the disease control population:

Patient Group	N	# of positives
Autoimmune liver disease	5	0
Viral hepatitis	31	2
Inflammatory bowel disease (Chron +UC)	17	0
H pylori infection	17	2
Food allergy	9	0
Systemic rheumatic disease	12	0
Autoimmune thyroid disease	22	0
Patients with gastrointestinal symptoms	11	0
Type 1 diabetes mellitus	14	0
Rheumatoid arthritis	37	1
Other infectious disease (HIV, Syphilis)	10	0
Total	**185**	**5**

Summary of sensitivity and specificity values in CD according to age groups:

Age group	DGP IgG	
	Sensitivity, %	Specificity, %
1 month – 2 years	66.7	94.6
2 years – 12 years	95.6	96.1
12-22 years	75.0	100.0
>21 years	89.4	97.8
< 21 years (total)	88.9	96.4
Total	89.2	97.3

Diagnostic sensitivity and specificity were calculated on the DH group separately, and the results are shown in the Table below.

Clinical sensitivity and specificity of the QUANTA Flash DGP IgG assay in DH:

		Diagnosis			Analysis (95% confidence)
		DH	Not DH	Total	
QUANTA Flash™ DGP IgG	Positive	16	9*	25	Sensitivity = 69.6% (47.1-86.8%)
	Negative	7**	327	334	Specificity = 97.3% (95.0-98.8%)
	Total	23	336	359	

*Two samples have H. pylori gastritis, two have viral hepatitis, and one has rheumatoid arthritis.

**Five samples were also negative on the DGP IgG EIA.

ROC analysis was performed on the validation sample pool for CD and DH (excluding CD patients on gluten-free diet). The results are below:

Celiac Disease:

Test	Area	95% CI	SE	Z	p
DGP IgG	0.99	0.98 to 1.00	0.004	127.74	<0.0001

Dermatitis Herpetiformis:

Test	Area	95% CI	SE	Z	p
DGP IgG	0.95	0.91 to 1.00	0.021	21.49	<0.0001

Stability

Shelf life

The QUANTA Flash DGP IgA and IgG assay kits, as well as the QUANTA Flash DGP IgA and IgG Calibrators and the QUANTA Flash DGP IgA and IgG Controls have a shelf life of one year.

In-use stability

The QUANTA Flash DGP IgA reagent cartridge in-use (on-board) stability is 40 days.
The QUANTA Flash DGP IgG reagent cartridge in-use (on-board) stability is 62 days.

Both the QUANTA Flash DGP IgA and IgG Calibrators can be used for up to 4 calibrations over an 8 hour period.

The QUANTA Flash DGP IgA and IgG Controls can be used for up to 15 times, with a maximum time of 10 minutes onboard the instrument per use. The total time the control tubes can be uncapped onboard the instrument is 2 ½ hours.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

OCT 23 2012

INOVA Diagnostics, Inc.
c/o Gabriella Lakos, M.D., Ph.D.
Director of Research, Rheumatology
9900 Old Grove Road
San Diego, CA 92131

Re: k113863
Trade/Device Name: QUANTA Flash™ DGP IgA
QUANTA Flash™ DGP IgA Calibrators
QUANTA Flash™ DGP IgA Controls
QUANTA Flash™ DGP IgG
QUANTA Flash™ DGP IgG Calibrators
QUANTA Flash™ DGP IgG Controls

Regulation Number: 21 CFR §866.5750
Regulation Name: Radioallergosorbent (RAST) Immunological Test System
Regulatory Class: Class II
Product Code: MST, JIX, JJX
Dated: September 20, 2012
Received: September 20, 2012

Dear Dr. Lakos:

This letter corrects our substantially equivalent letter of September 20, 2012.
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K113863

Device Name: QUANTA Flash™ DGP IgA Controls

Indications for Use:

The QUANTA Flash DGP IgA Controls are intended for quality control purposes of the QUANTA Flash DGP IgA chemiluminescent immunoassay (CIA) kit run on the BIO FLASH® Instrument that is used for the measurement of IgA anti-deamidated gliadin peptide (DGP) antibodies in human serum.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K113863

Indications for Use Form

510(k) Number (if known): K113863

Device Name: QUANTA Flash™ DGP IgG Controls

Indications for Use:

The QUANTA Flash DGP IgG Controls are intended for quality control purposes of the QUANTA Flash DGP IgG chemiluminescent immunoassay (CIA) kit run on the BIO FLASH® Instrument that is used for the measurement of IgG anti-deamidated gliadin peptide (DGP) antibodies in human serum.

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K113863

Indications for Use

510(k) Number (if known): k113863

Device Name: QUANTA Flash™ DGP IgA

Indications For Use:

The QUANTA Flash™ DGP IgA is a chemiluminescent immunoassay for the semi-quantitative determination of IgA antibodies to synthetic, deamidated gliadin peptides in human serum. The presence of IgA deamidated gliadin peptide antibodies can be used in conjunction with clinical findings and other laboratory tests to aid in the diagnosis of celiac disease and dermatitis herpetiformis.

Prescription Use ___X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K K113863

Indications for Use

510(k) Number (if known): k113863

Device Name: QUANTA Flash™ DGP IgG

Indications For Use:

The QUANTA Flash™ DGP IgG is a chemiluminescent immunoassay for the semi-quantitative detection of IgG antibodies to synthetic, deamidated gliadin peptides in human serum. The presence of IgG deamidated gliadin peptide antibodies can be used in conjunction with clinical findings and other laboratory tests to aid in the diagnosis of celiac disease in both IgA sufficient and IgA deficient subjects, as well as dermatitis herpetiformis.

Prescription Use ___X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K K113863

Indications for Use

510(k) Number (if known): k113863

Device Name: QUANTA Flash™ DGP IgA Calibrators

Indications For Use:

The QUANTA Flash™ DGP IgA Calibrators are intended for use with the QUANTA Flash™ DGP IgA chemiluminescent immunoassay to establish points of reference for the working curve that is used to determine Chemiluminescent Unit (CU) values in the measurement of IgA anti-DGP antibodies in serum.

Prescription Use ___X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K K113863

Indications for Use

510(k) Number (if known): k113863

Device Name: QUANTA Flash™ DGP IgG Calibrators

Indications For Use:

The QUANTA Flash™ DGP IgG Calibrators are intended for use with the QUANTA Flash™ DGP IgG chemiluminescent immunoassay to establish points of reference for the working curve that is used to determine Chemiluminescent Unit (CU) values in the measurement of IgG anti-DGP antibodies in serum.

Prescription Use ___X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K K113863